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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,256

04/17/2006

Fung-Lung Chung

11015-008

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29847 7590 07/16/2010
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EXAMINER

STONE, CHRISTOPHER R

ART UNIT

PAPER NUMBER

1628

MAIL DATE

DELIVERY MODE

07/16/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,256	Applicant(s) CHUNG ET AL.	
	Examiner CHRISTOPHER R. STONE	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed April 22, 2010, have been fully considered but are moot in view of new grounds of rejection. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1-17 are pending. Claims 15-17 are withdrawn from consideration as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Chung (Experimental Lung Research, Vol. 27, p. 319-330, 2001).

Claims 1-6, 9 and 12 are drawn to a method of inhibiting lung tumorigenesis in a mammal in need thereof, comprising administering an effective amount of an isothiocyanate conjugate at the post-initiation stage of tumor growth.

Chung teaches a method of inhibiting malignant lung tumorigenesis in a mammal (mouse) in need thereof, comprising orally administering an effective amount of an isothiocyanate conjugate (PEITC-NAC) at the post-initiation stage of tumor growth (p.

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326-328, Effects of ITC Conjugates During the Postinitiation Phase of NNK-Induced Lung Tumorigenesis heading and Table 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chung (Experimental Lung Research, Vol. 27, p. 319-330, 2001).

Chung teaches the aforementioned method, but does not expressly teach the administration of PEITC-NAC to humans (e.g. smokers and ex-smokers). However Chung expressly teaches that the ability of PEITC-NAC to inhibit tumorigenesis when administered following the exposure of a subject to a carcinogen (i.e. at the post-initiation stage of tumor growth) makes the compound useful in the chemopreventive

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therapy of smokers and ex-smokers (i.e. human subjects who have been exposed to carcinogens prior to treatment, p. 329, last two paragraphs). Therefore it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the method of Chung to inhibit tumorigenesis in human smokers and ex-smokers, since PEITC-NAC was known to be useful in the chemopreventive therapy of smokers and ex-smokers, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

Claims 10, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chung (Experimental Lung Research, Vol. 27, p. 319-330, 2001) in view of Lam (US 6,166,003).

Chung teaches the aforementioned method, but does not expressly teach the administration, but does not expressly teach the administration of PEITC-NAC in the form of tablets or capsules via the regimen of claims 11 and 13.

Lam teaches that the oral administration of isothiocyanate conjugates for the inhibition of tumorigenesis may be accomplished with tablet or capsule dosage forms at dosages of about 10 to 600mg, one to three times daily (abstract, column 9, lines 60-62 and column 11, lines 40-46). Therefore it would have been prima facie obvious to one of ordinary skill in the art to orally administer PEITC-NAC in tablet or capsule form at the instantly claimed dosages and daily frequency, since the dosage forms, dosages and administration frequency, were known in the art to be appropriate for the inhibition of tumorigenesis, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRS

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642